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| 10/017,798      | 12/12/2001  | Valentin Kramer      | 31567.3             | 9144             |

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EXAMINER

CHANG, VICTOR S

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1771

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

4

**Office Action Summary****Application No.**

10/017,798

**Applicant(s)**

KRAMER ET AL.

**Examiner**

Victor S. Chang

**Art Unit**

1771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.  
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-27, 32-34 and 37-42 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 19-27, 32-34 and 37-42 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.  
 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_.  
 5) ☐ Notice of Informal Patent Application (PTO-152)  
 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Introduction***

1. In view of the Appeal Brief filed on 4/27/2006, PROSECUTION IS HEREBY REOPENED. New grounds of rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. It is noted that claims 23-27 were rejected over prior art in the non-final action mailed 8/31/2005, but was inadvertently not included in the body of the Office action mailed 12/6/2005. The Examiner apologizes for the inadvertent error. The purpose of this Office is to provide a full account of the rejection of all the active claims over prior art. Additionally, in view of

Applicants' explanation regarding the questioned terms "intermediate node" and "third node" (see pages 6 and 7 of the Appeal Brief), the 112, 2<sup>nd</sup> paragraph rejection in Office action mailed 12/6/2005 is withdrawn.

***Claim Rejections - 35 USC § 112***

4. Claims 19 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For claim 19, the recitation "... a first plurality of fibrils interconnecting said first node with a said second node, said first plurality of fibrils defining a first group of pores therebetween, said **first group of pores** falling substantially within **first size range** ..." (emphasis added) appears to be vague and indefinite, because it is unclear what the term "size" is referring to, i.e., "size of an area" or "size of pores"? More particular, the recitation appears to define the term "first size range" as "an area contains the first group of pores", not as "pore size range of the first group of pores". Nonetheless, in order to expedite the prosecution, the present Office action presumes the term "first size range" as meaning "pore size range of the first group of pores", because otherwise there will be an issue of new matter (see also dependent claims 24-27). Similarly, the term "second size range" is interpreted as "pore size range of the second group of pores". Clarification is requested.

Claim 23 recites the limitation "said helical member" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

In claim 24, in the amendment filed 8/11/2005, the term “the small pores are” has been changed as “said first size range”; the term “the large pores are in the range” has been changed as “second range is”. Since there is no antecedent basis for the term “second range”, it is presumed to be “second size range” as recited in dependent upon claim 19.

Similar, in claim 25, the term “second range” lacks antecedent basis, and presumed to be “second size range”.

***Rejections Based on Prior Art***

5. Claims 19-22, 24-27 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwin et al. (US 6039755).

Edwin's invention relates to an expanded microporous tubular polytetrafluoroethylene (ePTFE) graft. The graft has a microstructure of nodes interconnected by fibrils. The nodes are elongated under radial expansion, and are substantially perpendicular to the longitudinal axis of the tubular ePTFE. The fibrils are oriented parallel to the longitudinal axis of the tubular ePTFE material (col. 2, lines 42-49; Figs. 1 and 2).

For claims 19-22, each of the micrographs in Figs. 18D, 21B and/or 21D shows the same general structural features as Fig. 2 of the present application (Applicants has stated that Fig. 2 is the basis of the recited structural features in claim 19. See reply filed 3/3/2005, page 3, and reply filed 10/27/2005, page 7), i.e., there are regions in which a plurality of interconnecting fibrils defining different pore sizes in different regions among large nodes and small nodes (intermediate nodes between the large nodes), the pattern of these different regions are repeated. The nodes are in general elongated and parallel to one another. Regarding the product-by-

process limitation "... article created by forming a mixture of a first resin and a second resin having a different molecular weight than said first resin, and then expanding said mixture", the examiner notes that since any polymeric material inherently comprises a distribution of molecular weights, i.e., comprising a mixture of molecules over a range of different molecular weights, this limitation is inherently anticipated by any polymeric material, including the ePTFE material of Edwin.

For claims 24-27, Edwin shows in Fig. 18D lengths of fibrils for small pores in the range of 2-15 mm, and lengths of fibrils for large pores in the range of 20-50 mm.

For claims 32-34, the microstructures in Figs. 18D, 21B and/or 21D read on the structural features of instantly claimed invention. It should be noted that the terms "first material" and "second material" are taken as meaning first and second "PTFE material" (see abstract of present application); and since Edwin's PTFE inherently has a molecular weight distribution, i.e., over a range of molecular weights, Edwin anticipates the terms "first material" and "second material" as claimed. Finally, regarding the use limitation "... for blood contact application" in claim 32, last line, since statements of intended use do not serve to distinguish structure over the prior art, it has not been given any patentable weight. See *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974).

### ***Response to Arguments***

6. Applicants argue that "... Edwin micrographs reveals substantially uniform internodal distances ... (see FIG. 2) ... creates corresponding uniformity in the pore sizes ... FIGs. 5-24 ...", and the structural limitations in claim 19 are not present in Edwin (Remarks, pages 7-10).

However, Edwin does show, at least, in Figs. 18D, 21B and/or 21D the microstructures as claimed, and corresponding structural features to Fig. 2 of present application can be easily identified by one of ordinary skill in the art of ePTFE.

Applicants argue that Edwin does not show two identifiable distinct groups of pores, and is less than specific in describing pore sizes (Remarks, page 10). However, at least Figs. 18D, 21B and/or 21D show all the corresponding features in Fig. 2 of the present application, and clearly illustrate the identifiable groups of pores, and the pore size ranges reading on the claimed ranges. Applicants' argument to the contrary is not well taken.

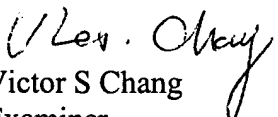
Applicants argue that Edwin's micrograph does not show a repeated structure-within-a structure arrangement (Remarks, page 11). In response, the Examiner asserts that identifiable repeated structure-within-a structure arrangement can be identified in Figs. 18D, 21B and/or 21D. In particular, Edwin's micrographs clearly bear the same general repeating structure-within-a structure features of the micrographs Figs. 3 and 4 of the present application. Applicants' argument to the contrary is not well taken.

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Victor S Chang  
Examiner  
Art Unit 1771

6/14/2006

  
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